

disposing said cardiac insert or implant in the patient's heart to reduce the volume of at least one ventricle of the patient's heart.

b³
26. The method defined in claim 25 wherein said cardiac insert or implant is a tensile member, further comprising attaching said tensile member to the patient's heart, and exerting tension on said tensile member to draw walls of the patient's heart towards one another.

REMARKS

Claims 1-12 and 19-26 are pending in the application, claims 13-18 being canceled and claims 20-26 being newly added herein. Claims 1, 9, 20, and 25 are the only independent claims.

Claims Rejections - Double Patenting

Claims 1-19 stand rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,258,021.

This rejection was made in a prior Office Action. In response to that prior rejection of claims 1-19 under the judicially created doctrine of obviousness type double patenting, applicant submitted a Terminal Disclaimer duly executed by the undersigned attorney of record for applicant.

The Examiner contends that the submitted Terminal Disclaimer does not comply with 37 C.F.R. § 1.321(b) and/or 1.321© because the person who has signed the disclaimer has not stated the extent of his/her interest, or the business entity's interest, in the application/patent.

Applicant respectfully traverses the Examiner refusal to recognize the previously submitted Terminal Disclaimer and maintains that the previously submitted Terminal Disclaimer complies with the requirements of 37 C.F.R. § 1.321(b) and 1.321(c). The Examiner particularly refers to 37 C.F.R. § 1.321(b)(3) in maintaining the obviousness-type double patenting rejection. However, that rule does **not** require that the signatory indicate his or her interest in any application or patent referred to in a terminal disclaimer. Instead, 37 C.F.R. § 1.321(b)(3) provides that a terminal disclaimer must “state the present extent of *applicant’s* or *assignee’s* ownership interest in the patent to be granted” (emphasis added). In the present case, the previously submitted Terminal Disclaimer clearly stated the interest of the assignee, Wilk Patent Development Corporation, in the instant application and Patent No. 6,258,021. The assignee “is the owner of application No. 09/435,525 filed November 8, 1999 ... [and] ... is also the owner of U.S. Patent No. 6,258,021”

It is to be noted that 37 C.F.R. § 1.321(b)(1) states that the signatory must be one of four classes of individuals connected with the prosecution of the application. This rule impliedly requires that the **status** of the signatory be indicated in a terminal disclaimer to clarify that the individual has the requisite authority. The status of the signatory of the previously submitted Terminal Disclaimer was indicated as “Attorney for Applicant” pursuant to 37 C.F.R. § 1.321(b)(1)(iv).

For these reasons, the previously submitted Terminal Disclaimer is believed to comply with the requirements of 37 C.F.R. § 1.321.

Claims Rejections - 35 U.S.C. § 102

Claims 1-19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,961,440 to Schweich, Jr. et al. ("Schweich").

Claim 1 Applicant respectfully traverses the rejection of claim 1 under § 102(b). As set forth in claim 1, a method for improving cardiac function comprises inserting a tensile member into a patient, and inserting the tensile member into the patient's heart so as to compress and **close off lower portions of both** ventricles of the heart.

The Schweich patent discloses a method of reducing ventricular volume, particularly the volume of the left ventricle. Tensile members (e.g., 18, 118, 218, 318, 418, 518, 618, 64, 164) traverse a ventricular chamber for holding opposing walls of the chamber closer to one another, thereby reducing ventricular volume. However, there is nothing in the Schweich patent which discloses or suggests **closing off the lower portions of both** ventricles of the heart, as illustrated exemplarily in applicant's Figure 3B and 4F. Schweich discloses one embodiment (Figure 4) where a side wall of the left ventricle is pinched and closed off, but does not suggest closing off the lower portion of the ventricle or the lower portions of both ventricles.

Claim 9 As recited in amended claim 9, a method for reducing ventricular volume comprises inserting a flexible catheter into a ventricle of a patient's heart, deploying a cardiac insert or implant from a leading end of said catheter, and disposing said cardiac insert or implant in the patient's heart to reduce the volume of at least one ventricle of the patient's heart.

Schweich describes a method of ventricular volume reduction wherein a rigid member in the form of a needle is forced through the heart to place a tensile member across a chamber of the

heart. See Figures 24-26. Schweich's method would not work if the needle were a flexible member. Accordingly, Schweich teaches away from the invention as set forth in amended claim 9.

Claim 20 As set forth in new independent claim 20, a method for reducing ventricular volume comprises inserting a catheter into a ventricle of a patient's heart, deploying a cardiac insert or implant from a leading end of the catheter while the leading end is disposed in the patient's heart, and disposing the cardiac insert or implant in the patient's heart to reduce the volume of at least one ventricle of the patient's heart.

In the method disclosed by Schweich, a cardiac insert is ejected from a free end of a needle only after the needle tip has passed through the heart. Thus, the cardiac insert or tensile member is ejected or deployed from a leading end of the needle only when that leading end is located outside of the patient's heart. Nothing in the teachings or implications of Schweich would provide any impetus or motivation to one of ordinary skill in the art to deploy a cardiac insert or tensile member from a leading end of the needle while that leading end is located inside the patient's heart.

Claim 25 As set forth in new independent claim 25, a method for reducing ventricular volume comprises inserting a catheter through a patient's vascular system into a ventricle of the patient's heart, deploying a cardiac insert or implant from a leading end of the catheter, and disposing the cardiac insert or implant in the patient's heart to reduce the volume of at least one ventricle of the patient's heart.

The rigid needle of Schweich is inserted through the heart from the intrapericardial space.

That needle could not be inserted percutaneously, i.e., through the vascular system. Thus, Schweich teaches away from the invention as set forth in independent claim 25.

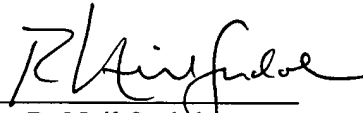
Conclusion

For the foregoing reasons, independent claims 1, 9, 20, and 25, as well as the claims dependent therefrom, are deemed to distinguish over the art of record. Also, the obviousness-type double patenting rejection of claims 1-19 is deemed to have been overcome by the previous submission of a Terminal Disclaimer. Accordingly, claims 1-12 and 19-26 appear to be in condition for allowance. An early Notice to that effect is earnestly solicited.

Should the Examiner believe that direct contact with applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

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APPENDIX TO AMENDMENT IN APPLICATION NO. 09/435,525
SHOWING MARKED UP VERSIONS OF AMENDED CLAIMS

Amend claim 9 as follows:

9. (Once Amended) A method for reducing ventricular volume, comprising:
inserting a flexible catheter into a ventricle of a patient's heart;
deploying a cardiac insert or implant from a leading end of said catheter; and
disposing said cardiac insert or implant in the patient's heart to reduce the volume of at
least one ventricle of the patient's heart.

Amend claim 19 as follows:

19. (Once Amended) The method defined in claim [14] 2 wherein said [instrument]
catheter is inserted into the patient through the vascular system of the patient.

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